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Ms. Katherine Benham
USDA-AMS-TMD-NOP
1400 Independence Avenue, SW.
Room 4008—So., Ag Stop 0268
Washington, DC 20250—0200

Dear Ms. Benham:

I was a Charter Member of the National Organic Standards Board, hereinafter referred to as “the NOSB”, and served a three-year term from 1992 to early 1994. I chaired the NOSB Processing, Handling, and Labeling Committee during those three years. Thereafter, at the request of the National Organic Program (NOP), I facilitated two NOSB sessions on substances proposed for the National List. I have been a TAP reviewer on sundry processing substances since then, working with various contractors and directly with NOP (boiler additives). My formal scientific training is in Chemistry (B.S. degree) and Biochemistry (M.S. and Ph.D. degrees). I specialize in nutrition, particularly infant nutrition, and worked in private industry for thirty-five years. I am a registered patent agent. Currently I am a consultant.

I wish to comment on the recommendation prepared by the NOSB Materials Committee to clarify the statutory definition of the term “synthetic.”

The Organic Food Production Act of 1999 (U.S.C. 6501), hereinafter referred to as “the Act”, endowed the NOSB with broad responsibilities and unusual powers for a Federal Advisory Committee. The specific responsibilities of the NOSB are established in Section 6518 of the Act; see Appendix A. In its diligent work over the years to carry out faithfully its responsibility under the Act to develop the proposed National List and proposed amendments to the National List for submission to the Secretary, the NOSB has acted as Prosecutor, Judge, and Jury for petitioned substances.

Section 6518 (k)(3) of the Act, which empowers the NOSB to convene technical advisory panels to evaluate substances, created specific authority for the “Prosecutor” role of the NOSB.

Section 6518(k)(2), which requires the NOSB to develop the proposed National List or proposed amendments to the National List in accordance with the criteria in Sections 6517 and 6518 of the Act, created specific authority for the “Jury” role of the NOSB.

However, in acting as “Judge” by assuming the role of “interpreter” of the statutory definition of the term “synthetic,” I believe that the NOSB has exceeded its competence. As a Charter member of the NOSB and an ex-NOSB member facilitator of material

discussions of early NOSB deliberations, I am fully aware that the NOSB was forced by expediency to judge the meaning of the term “synthetic” in order to make a decision on the synthetic or non-synthetic nature of substances proposed for the National List. However, the NOSB is not the appropriate entity to interpret statutory terms and exceeds its competence when it does so.

In the Act, Congress statutorily defined the term “synthetic” for the purpose of the organic food regulations. The Supreme Court of the United States has ruled that the interpretation of statutory terms and definitions is a question of law for a judge to decide and not a question of fact for a jury to decide. *McDERMOTT INTERNATIONAL, INC. v. WILANDER*, 498 U.S. 337 (1991)¹. Similarly, in patent-related matters, the Supreme Court holds that claim construction – the meaning of language - is a matter of law for the judge rather than a matter of fact for the jury. “The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis.” *MARKMAN v. WESTVIEW INSTRUMENTS, INC.*, 517 U.S. 370 (1996).²

Accordingly, in the implementation of the Act, the meaning of the term “synthetic” is a question of law, to be settled ultimately by a judge and dependent on the statutory definition established by Congress in the Act and the ordinary meaning of words as found in a dictionary.

Historically, the NOSB has acted as a Jury by “voting” to decide what was “synthetic” and what was not, but the NOSB has not interpreted the statutory definition of “synthetic” consistently. Some outcomes of this voting, are, in the opinion of some of us, wrong, such as deciding that “cream of tartar” (“potassium acid tartrate”) - the crystals that form spontaneously and naturally in wine during the wine fermentation process - is a synthetic substance: 7CFR205.605(b)(23).

Other statutory terms in the Act, such as “heating,” [Section 6502 DEFINITIONS (17) Processing³] also have been arbitrarily interpreted by the NOSB. Using the temperature

¹ “It is for the court to define the statutory standard. “Member of a crew” and “seaman” are statutory terms; their interpretation is a question of law. The jury finds the facts and, in these cases, applies the legal standard, but the court must not abdicate its duty to determine if there is a reasonable basis to support the jury’s conclusion.” *McDERMOTT INTERNATIONAL, INC. v. WILANDER*, 498 U.S. 337 (1991)

² “The two elements of a simple patent case, construing the patent and determining whether infringement occurred, were characterized by the former patent practitioner, Justice Curtis. ‘The first is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them. The second is a question of fact, to be submitted to a jury.’ *Winans v. Denmead*, 15 How., at 338; see *Winans v. New York & Erie R. Co.*, 21 How., at 100; *Hogg v. Emerson*, supra, at 484; cf. *Parker v. Hulme*, supra, at 1140.” *MARKMAN v. WESTVIEW INSTRUMENTS, INC.*, 517 U.S. 370 (1996)

³ “PROCESSING. The term “processing” means cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.” Section 6502 DEFINITIONS (17).

achievable in a home oven as the upper limit on “heating” is a distinction found neither in the Act nor in the dictionary. A human food⁴ such as oyster shell or limestone must be heated to higher temperatures than those found in a contemporary home oven to create the roasted limestone⁵ used for thousands of years by Mesoamericans to make their native grain maize more nutritious⁶ and to avoid the vitamin deficiency disease pellagra.

The NOSB should welcome relinquishing the judicial task of interpreting the definitions and terms in the Act. It has been a thankless task.

If the NOSB should not interpret the meaning of a statutory term in the Act, who should be the initial arbiter prior to judicial challenge? In my opinion, it must be the Secretary. Presumably, the Secretary will rely on the Office of General Counsel in the Department, since this office has legal competence and the burden of defending the interpretation when challenged in court. The “interpretation” should be in the form of formal instructions similar to those given by a judge to a jury in a criminal or a civil trial.

Consequently, the Secretary should find the recommendations of the NOSB Material Committee concerning the meaning of the term “synthetic” to be valuable input, consistent with the responsibility of the NOSB “to advise the Secretary on any other aspects of the implementation of this chapter.” 7 U.S.C. Section 6518(k)(1).

Thank you for the opportunity to comment on this issue.

Sincerely,

Richard C Theuer, Ph.D.

⁴ Food: any substance taken into and assimilated by a plant or animal to keep it alive and enable it to grow. Webster's New World Dictionary of the American Language.

⁵ Nixtamalization is an ancient process. It consists of heating a mixture of one part maize grain added to two parts of a one-percent alkaline limestone solution to 80°C for 20 to 45 minutes, and then allowing it to stand overnight. The grain pericarp or seed-coat gets hydrolyzed and separated from the grain as the cold cooking liquor is decanted. The solid material now referred to as nixtamal is washed two or three times with water to remove the seed-coats, tip caps, excess limestone and any impurities in the grain. Nixtamal is ground, kneaded to dough and roasted in flattened, individual portions over a heating pan (tortilla). Nixtamalization significantly improves the bioavailability of calcium. This fact has important consequences in the Mesoamerican diet, based on tortillas, because nixtamalized maize provides most of the calcium needed by the human organism. Source: A. Turrent and J.A. Serratos “Context and Background on Wild and Cultivated Maize in Mexico.” Ch 1 in Maize and Biodiversity: The Effects of Transgenic Maize in Mexico: Key Findings and Recommendations. North American Commission for Environment Cooperation (2004); available at <http://www.cec.org>.

⁶ Boiling maize kernels in mineral lime (roasted calcium carbonate) loosens the glume from the kernel, making maize more digestible and easier to grind. The lime also releases the niacin (a B-complex vitamin) in maize to the digestive system, which prevents pellagra, a niacin-deficiency disease. Also, the lime adds calcium to the diet and builds strong bones and teeth.
http://www.indiana.edu/~arch/saa/matrix/ma/ma_mod06.html

Appendix A: Responsibilities of the National Organic Standards Board
Organic Food Production Act of 1990

Sec. 6518

(a) In General. The Secretary shall establish a National Organic Standards Board to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this chapter.

(k) Responsibilities of the Board.

(1) In General. The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.

(2) National List. The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 6517 of this chapter.

(3) Technical Advisory Panels. The Board shall convene technical advisory panels to provide scientific evaluation of the substances considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.

(4) Special Review of Botanical Pesticides. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances.

(5) Product Residue Testing. The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

(6) Emergency Spray Programs. The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this chapter (except the provisions of section 6511 of this chapter) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

(l) Requirements. In establishing the proposed National List or proposed amendments to the National List, the Board shall -

(1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;

(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and

(3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

(m) Evaluation. In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider -

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

(4) the effect of the substance on human health;

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

(6) the alternatives to using the substance in terms of practices or other available materials; and

(7) its compatibility with a system of sustainable agriculture.

(n) Petitions

The Board shall establish procedures under which persons may petition the Board for the purpose of evaluating substances for inclusion on the National List.

(o) Confidentiality

Any confidential business information obtained by the Board in carrying out this section shall not be released to the public.